Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	7160.01
True Name	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovilis Vision 8 - Intervet Veterinaria Chile Ltda VISION 8 - Merck Sharp & Dohme Saude Animal Ltda. Vision 8 with SPUR - Merck Animal Health Vision 8 with SPUR - No distributor specified
Date of Compilation Summary	June 05, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei*
Study Purpose	To demonstrate effectiveness against disease caused by *C. chauvoei*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 13, 1993

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei, C. septicum, C. novyi, C. sordellii, C. perfringens* Type C & D
Study Purpose	Effectiveness against disease caused by *Clostridium chauvoei, C. septicum, C. novyi, C. sordellii and C. perfringens* Type C & D
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.

Study Type	Efficacy
Pertaining to	*Clostridium haemolyticum*
Study Purpose	To demonstrate effectiveness against disease caused by *C. haemolyticum*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 13, 1993

Study Type	Efficacy
Pertaining to	*Clostridium haemolyticum*
Study Purpose	Effectiveness against disease caused by *Clostridium haemolyticum*
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.

Study Type	Efficacy
Pertaining to	*Clostridium novyi*
Study Purpose	To demonstrate effectiveness against disease caused by *C. novyi*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 13, 1993

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type C
Study Purpose	To demonstrate effectiveness against disease caused by *C. perfringens* Type C
Product Administration	Subcutaneous or Intramuscular
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 13, 1993

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type D
Study Purpose	To demonstrate effectiveness against disease caused by *C. perfringens* Type D
Product Administration	Subcutaneous or Intramuscular
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 13, 1993

Study Type	Efficacy
Pertaining to	*Clostridium septicum*
Study Purpose	To demonstrate effectiveness against disease caused by *C. septicum*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 13, 1993

Study Type	Efficacy
Pertaining to	*Clostridium sordellii*
Study Purpose	To demonstrate effectiveness against disease caused by *C. sordellii*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 14, 1998

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 2, 1992

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.